Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
RIOS :004USC2

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on October 12, 2007

Signature

Typed or printed name Travis M. Wohlers

Application Number	Filed
10/667,534	09/22/03

First Named Inventor
Adan Rios

Art Unit	Examiner
1648	Jeffrey S. Parkin

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 57,423

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Travis M. Wohlers
Typed or printed name

512-536-5654
Telephone number

October 12, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

Arguments in Support of Pre-Appeal Brief Review for Application Serial No. 10/667,534

A. The Objection Under 37 C.F.R. § 1.75(c) is Legally Unsupported

The Examiner's objection to claims 40-47 under 37 C.F.R. § 1.75(c) as being of improper dependent form because they refer back to a numerically following claim is legally unsupported. The MPEP states that "in situations where a claim refers to a numerically following claim and the dependency is clear, both as presented and as it will be renumbered at issue, all claims should be examined on the merits and no objection as to form need be made. In such cases, the examiner will renumber the claims into proper order at the time the application is allowed." MPEP § 608.01(n)(F) (emphasis added). Although claims 39-47 depend, either directly or indirectly, from claim 48, their dependency is clear. The objection should be withdrawn and that the claims be renumbered at issue.

B. The Claims Are Supported by Adequate Written Description in the Specification

The Examiner alleges that the specification's working examples with HIV reverse transcriptase (RT) do not adequately support the genus of viral particles and RT proteins encompassed by the current claims. The Examiner's position is factually and legally incorrect.

A unique aspect of retrovirus replication is the conversion of a single-stranded RNA from the virus genome into a double-stranded DNA molecule that must integrate into the genome of the host cell prior to the synthesis of viral proteins and nucleic acids (Specification, p. 3, ln. 4-12). Accordingly, all retroviruses possess a reverse transcriptase enzyme, which converts the RNA of their genetic material into DNA. The present specification teaches that a reverse transcriptase may be inactivated by binding the reverse transcriptase with one or more azido-labeled compounds and then irradiating it (*see e.g.*, p. 12, ln. 8-9). Since retroviruses, such as HIV, cannot integrate into the genetic machinery of the host cell without reverse transcription, the inhibition of reverse transcriptase has a universal consequence on the inability of any

retrovirus to integrate within the genetic machinery of a suitable host cell. Thus, the inactivation of reverse transcriptase as described in the present specification would be understood by a person of ordinary skill in the art to be applicable to any viral particle comprising a reverse transcriptase. Moreover, the present specification specifically states that "the methodology of the present invention is applicable to any retrovirus which may be associated with any animal or human disease as a method for development of effective immunogens and preventative vaccines. Thus, the present invention has a broader applicability than the exemplified HIV vaccine." (Specification, pg. 16, ln. 20-23).

Furthermore, since all reverse transcriptases prime the synthesis of new DNA from a RNA molecule with abundant secondary structure strongly associated with the enzyme (in the large majority of cases a tRNA), it is accepted that the catalytic unit among reverse transcriptases is phylogenetically conserved. Applicants response filed March 5, 2007, provided a number of publications describing the conservation of reverse transcriptases. (*see e.g.*, IDS references C133-C140). Thus, for this additional reason it would have been understood by a person of ordinary skill in the art at the time of filing that the inactivation of reverse transcriptase as described in the present specification would be applicable to any reverse transcriptase.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventors had possession of the claimed invention. Furthermore, it is not necessary that every permutation within a generally operable invention be effective for Applicant to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention. *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). As set forth above, a person of ordinary skill in the art would reasonably conclude that the inventor had possession of the currently claimed invention at the time of filing based on the description provided for in the specification.